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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-----------------------|---------------------|------------------|
| 10/643,141 | 08/18/2003 | Stephen L. Hutcherson | C01037.70049.US | 3287 |

7590 05/16/2007
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| EXAMINER |
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GUSSOW, ANNE

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| ART UNIT | PAPER NUMBER |
| 1643 | |

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| MAIL DATE | DELIVERY MODE |
| 05/16/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/643,141 | Applicant(s) HUTCHERSON ET AL. | |
| | Examiner Anne M. Gussow | Art Unit 1643 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>4/16/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 16, 2007 has been entered.

2. Claim 38 has been amended.

Claims 26-48 are under examination.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on April 16, 2007 has been fully considered by the examiner and an initialed copy of the IDS is included with this Office Action.

Rejections Withdrawn

4. The rejection of claims 26-48 under 35 U.S.C. 112, first paragraph, as containing new matter has been withdrawn in view of applicant's arguments.

Rejections Maintained

5. The rejection of claims 26-48, under 35 U.S.C. 112, first paragraph, as lacking written description is maintained.

The response filed April 16, 2007 has been carefully considered but is deemed not to be persuasive. The response states that the specification describes a class of oligonucleotide analogs with at least one phosphorothioate bond in the backbone described in terms of structure and structure/function correlation (see response page 6). In response to this argument, as cited in the prior office action, and supported by McIntyre, et al., not all oligonucleotides elicit an immune response. The specification describes non-sequence specific immune stimulation by phosphorothioate oligonucleotide analogs however; the specification does not provide support as to the necessary structure of the oligonucleotide to stimulate an immune response. For example, is the immune response dependent upon the position of the phosphorothioate or the length of the oligo or the overall structure of the oligo?

6. The rejection of claims 26-48, under 35 U.S.C. 112, first paragraph, as lacking enablement is maintained.

The response filed April 16, 2007 has been carefully considered but is deemed not to be persuasive. The response states that the specification describes a class of molecules and applicant is not required to provide a working example for each and every species in order to enable the genus (see response page 8). In response to this argument, enablement of a genus is not dependent upon working examples of each and

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every species, if one skilled in the art would expect the claimed genus could be used in that manner without undue experimentation (see MPEP 2164.03), however, in regards to in the instant genus, in addition to the arguments set forth in previous office actions Crooke (Bio/technology, 1992. Vol.10 No. 8, pages 882-886) teach the activity of ISIS1082 to be equivalent to trifluorothymidine in cornea of mice, but less active in other animal models (page 885, first column). Also, the specification discloses the phosphorothioate molecules to be antisense or complementary to viral RNAs; thus the oligos used in the examples cannot be not-antisense as claimed and the closest prior art (Branda, et al., see below) teaches phosphorothioate oligos that are antisense to the rev region of the HIV genome. Regarding simulating an immune response in a patient who has cancer, has an infection, or is having surgery, molecule inducing an immune stimulus against a viral infection would not necessarily induce an immune stimulus effective against a cancer cell. Therefore, since applicant's example using a single species of a broad genus to induce an immune response in a single disease model (genital warts, see examples 11 and 12) does not provide sufficient enablement for inducing an immune response with just any non-antisense phosphorothioate oligonucleotide in just any of a broad genus of cancer, infection or surgery, after a fresh consideration of the claims the rejection is maintained.

7. The rejection of claims 26, 28, 29, and 30 as being unpatentable over claims 1-8 of US Patent 6,727,230 (Hutcherson, et al.) in view of US PAT 5,356,882 (Walker et al.) is maintained.

The response filed April 16, 2007 has been carefully considered but is deemed not to be persuasive. The response states "applicants may consider filing a terminal disclaimer if some claims are found to be allowable." (see response page 9) In response to this argument, the terminal disclaimer has not been filed and the rejection is maintained for the reasons set forth in an earlier Office Action. The examiner would like to make note of a typographical error in the Walker patent number listed in applicant's response. The correct patent number is listed above.

New Grounds of Objection/Rejection

Specification

8. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the phrase "wherein the phosphorothioate oligonucleotide is not antisense" in claim 26, line 6 ^{LACKS ANTISENSE BASIS} ~~is not supported~~ in the specification. LR

Conclusion

9. No claims are allowed.

10. Claims 26-48 are free of the prior art. The closest prior art is Branda, et al. (Biochemical Pharmacology, 1993. Vol. 45 No. 10, pages 2037-2043). Branda, et al. teach stimulation of an immune response in mice by administering an anti-sense phosphorothioate oligo that is antisense to the rev region of the HIV genome. Branda,

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et al. do not teach or reasonably suggest stimulation of an immune response with a phosphorothioate that is not antisense.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow, Ph.D.

May 9, 2007


LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER